

## REMARKS

Claims 1, 3-22 and 37 are pending. Claims 1, 16 and 37 are currently amended. Claims 2 and 23-36 have been cancelled. Claims 1 and 16 have been amended to indicate that the solid core is comprised of a metal or an alloy. Support for this amendment can be found at page 8, lines 27-28 of the specification. Claim 37 has been amended to clarify the claimed invention.

Applicant believes that the originally presented claims drawn to a filamentary structure comprising a solid core are non-obvious and non-anticipated by the cited art. However, in order to advance prosecution, Applicant has filed a Request for Continued Examination herewith. In view of the arguments asserted in the Response under 37 C.F.R. §1.116, the amendments and the arguments asserted herein, and the declaration under 37 C.F.R. §1.132 accompanying this response, Applicant respectfully requests withdrawal of the pending rejection and allowance of the claims.

In the Advisory Action, the Examiner indicated that the amendments would not be entered because they were deemed not to place to application in better form for appeal by materially reducing or simplifying the issues for appeal. The Examiner asserted that that U.S. Patent No. 5,486,593 to Tang et al. ("Tang") teaches fibers that can be solid (Col. 6, line 57) and coated with other polymers (Col. 7, line 36) and conductive agents (Col. 19, line 1). The Examiner asserted that no superior or unexpected results of record showed the criticality of the core made of metal or metal alloy.

Applicant respectfully submits that it does not need to submit evidence of secondary considerations of nonobviousness because the Examiner has not set forth a *prima facie* case of obviousness with respect to the amended claims. MPEP §2141.03 states:

“To establish a *prima facie* case of obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art.” *In re Royka*, 490 F2d 981, 180 U.S.P.Q. 580 (CCPA 1974). “All words in a claim must be considered in judging the patentability of that claim against the prior art.” *In re Wilson*, 424 F2d 1382, 165 U.S.P.Q. 494, 496 (CCPA 1970).

Applicant respectfully submits that the Final Office Action and the Advisory Action have failed to set forth a *prima facie* case of obviousness for the claims, as amended, as the combined references fail to disclose all the limitations of the claimed invention. Amended claim 1 includes the limitation “wherein the solid core comprises a metal or an alloy.” This limitation is not taught by any of the cited references.

Tang discloses bioabsorbable polymers on objects (e.g. Col. 5, lines 49-51) made of metals (e.g. Col. 19, lines 40-42), yet none of these metal objects were metal wire, needles, or filaments. (Declaration of Thomas Barrows (“Barrows Decl.”), ¶ 6.) In fact, Tang’s bioabsorbable polymer coatings were used only on woven or knitted fibers, and were used only for the purpose of sealing non-bioabsorbable vascular grafts against fluid leaks during surgery. (Id.) Such vascular grafts are constructed from synthetic polymer fibers and not from metal filaments. (Id.) The present invention, by contrast, uses single metal filaments in combination with bioabsorbable polymers for the purpose of penetration of skin, to deliver the coating and its cells or other agents into the living tissue of the recipient. (Barrows Decl., ¶ 7.) Moreover, the use of metal filaments, or for that matter, any material which might damage tissue would most certainly not be within the disclosure or contemplation of Tang. (Barrows Decl., ¶ 6.)

In order to generate the interconnecting pores of the claimed filament, the heat applied to the coated filament must penetrate the filament quickly. (Barrows Decl., ¶ 8.) The claimed metal or metal alloy core, unlike a nonmetallic core, conducts heat rapidly into the center of the filament during thermal activation of the blowing agent. (Id.) The end result is

a coating reticulated with interconnecting pores as desired. (Id.) The kind of materials suggested by Tang would not and could not be used to create the porous coating of the present invention, because the materials suggested by Tang, i.e. ones which cause no tissue or organ trauma, are not sufficiently thermally conductive to be used in the presently claimed invention. (Id.)

Moreover, the exceptional strength and toughness of metal as a core material in the presently claimed invention in comparison to other materials is critically important, especially in this case where the core is a very fine diameter filament, because the filament must be capable of easily penetrating the skin. (Barrows Decl., ¶ 9.) As noted above, Tang's applications necessarily require minimization of tissue trauma, and therefore the disclosed filaments would not be useful for the applications of the presently claimed invention.

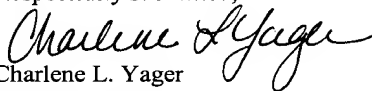
Applicant respectfully submits that the Examiner has clearly used impermissible hindsight reconstruction based on Applicant's invention to arrive at the presently claimed invention using the cited references. "The mere fact that the references can be combined or modified does not make the resultant combination obvious unless the prior art also suggests the desirability of the combination." MPEP 2143.01, citing *In re Mills*, 916 F.2d 680 (Fed. Cir. 1990). There is no suggestion to modify the disclosure of Tang to arrive at the presently claimed filaments. The utility of Tang would not suggest the substitution of a metal core in the disclosed polymer-based filaments.

Furthermore, in the present invention, it is desirable for the core to be removed from the coating, either before or after the product is implanted into the living tissue. (Barrows Decl., ¶ 10.) If the core filament is metal, there is a high degree of certainty that the removal process will be successful. (Id.) If any other material is used, there is a risk that the filament will break under tension, making complete removal of any broken fragments difficult and impractical. (Id.) The presence of non-bioabsorbable debris in the porous bioabsorbable polymer scaffold implantation site is not desirable. (Id.)

Thus, Applicant respectfully submits that the claims as amended are not obvious in view of Tang. Tang does not disclose or suggest the presently claimed invention to one of ordinary skill in the art because it does not teach or suggest a filament with a metal or metal-alloy core.

In light of the foregoing, Applicant respectfully requests that the newly amended claims are in condition for allowance. Thus, Applicant earnestly solicits a Notice of Allowance.

Respectfully submitted,

  
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